

Attachment 11

Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report

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general cancer statement) or replaced a randomly selected TCA statement when the revised statement did not have a TCA counterpart (e.g., a revised statement on diabetes replaced the TCA statement on fatal lung disease in smokers).

After viewing each warning statement, participants answered questions about that statement before viewing and answering questions about the next assigned warning statement. Questions were designed to measure several study outcomes, including:

- whether the warning statement was new information to participants (*"New information"*);
- whether participants learned something from the warning statement (*"Self-reported learning"*); and
- whether the warning statement made participants think about the health risks of smoking (*"Thinking about risks"*).

After viewing and answering questions about all 9 warning statements individually, participants answered questions about another study outcome: beliefs about the link between smoking and each of the health consequences presented in the warning statements they viewed (*"Health beliefs"*).

In Phase 2, all participants viewed 9 warning statements presented at the same time. Participants assigned to the control condition viewed the 9 TCA warning statements again. Participants assigned to the treatment conditions viewed one of several different combinations of 9 revised warning statements. After viewing the 9 warning statements, all participants answered questions about their beliefs about the link between smoking and each of the health consequences presented in the warning statements.

Overview of Statistical Analyses: Analyses compared the responses from participants in each of the treatment conditions to responses from participants in the control condition for the Phase 1 outcomes to assess effects associated with the revised statements and the TCA statements. These analyses examined whether, relative to viewing a TCA warning statement, viewing a revised warning statement resulted in statistically significantly higher levels of the outcomes measured (e.g., *New information*, *Self-reported learning*).

Analyses of Phase 2 outcomes compared responses from all participants in the treatment conditions to the responses from all participants in the control condition. These analyses examined whether, relative

to viewing all 9 TCA warning statements, viewing any combination of 9 revised warning statements resulted in statistically significantly higher levels of the outcome measured (e.g., *Health beliefs*).

Aligning Interpretation of Results with Study Purpose: Because the purpose of the study was to determine which, if any, revised warning statements promote greater public understanding of the risks associated with cigarette smoking when compared to a TCA warning statement, the study was not designed to “rank order” the revised warning statements or compare individual results of one revised warning statement to another. Rather, we interpreted the presence of a statistically significant finding in a positive direction as support for the revised warning statement over its comparator TCA statement, without comparing the size of each effect. This interpretation approach also recognizes that 5 of the 15 revised warning statements did not have a comparator TCA warning statement on the same health topic and were compared to a randomly selected TCA statement on a different health topic, which may have resulted in larger effects for these revised statements.

While the study was designed to measure a range of outcomes related to public understanding, *New information* and *Self-reported learning* are predictive for the task of determining which, if any, of the revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to a TCA statement. An important first step in promoting public understanding of health risks is to raise public awareness of those risks, particularly if the risks are not commonly known.^{1 2} Measuring whether information is new helps identify opportunities to improve public understanding through increased awareness. Additionally, communication science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning.³ Thus, *New information* and *Self-reported learning* are often linked and are both potential indicators of improved understanding.

¹ CDC. Best practices for comprehensive tobacco control programs—2014. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at http://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm.

² Weiss JA, Tschirhart M. Public information campaigns as policy instruments. *J Policy Anal Manage*. 1994; 13(1), 82-119.

³ e.g., Duke JC, Alexander TN, Zhao X, Delahanty JC, Allen JA, MacMonegle AJ, Farrelly, MC. Youth's awareness of and reactions to the real cost national tobacco public education campaign. *PLoS One*. 2015;10:e0144827

to viewing all 9 TCA warning statements, viewing any combination of 9 revised warning statements resulted in statistically significantly higher levels of the outcome measured (e.g., *Health beliefs*).

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While the study was designed to measure a range of outcomes related to public understanding, *New information* and *Self-reported learning* are predictive for the task of determining which, if any, of the revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to a TCA statement. An important first step in promoting public understanding of health risks is to raise public awareness of those risks, particularly if the risks are not commonly known.^{1 2} Measuring whether information is new helps identify opportunities to improve public understanding through increased awareness. Additionally, communication science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning.³ Thus, *New information* and *Self-reported learning* are often linked and are both potential indicators of improved understanding.

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² Weiss JA, Tschirhart M. Public information campaigns as policy instruments. *J Policy Anal Manage*. 1994; 13(1), 82-119.

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Additionally, these two outcomes can show greater effects after a single exposure, whereas communication science research indicates repeated exposures over time are typically required to change beliefs (i.e., *Health beliefs*).

Summary of Results: In general, TCA warning statements were new information to relatively few participants; revised warning statements on the same health topics as those included in the TCA warning statements were new information to more participants than the TCA warning statements; and revised warning statements that focused on health topics not included in the TCA were new information to most participants. For example, fewer than 24% of participants reported that the TCA warning statements were new information to them,⁴ whereas more than 66.2% of participants that viewed revised warning statements that focused on health topics not included in the TCA (e.g., blindness, diabetes) reported the statements were new information to them. When a specific health topic was covered by both a revised and TCA warning statement (e.g., cancer), the revised warning statement was new information to more participants than the TCA warning statement. For *Thinking about risks* and *Health beliefs*, levels of both outcomes were generally high for both TCA and revised warning statements, with a few differences demonstrating that the revised statements had higher levels of these outcomes than the TCA statements overall. However, as previously noted, the *New information* and *Self-reported learning* outcomes measured in Phase 1 of the study are more closely aligned with the purpose of this study and provide the most useful data for determining whether a revised warning statement would promote greater understanding of the risks associated with cigarette smoking.

At the level of the individual warning statement, 10 of the 15 revised warning statements tested demonstrated statistically significant higher levels of both *New information* and *Self-reported learning* when compared to a TCA warning statement. Those 10 revised warning statements focused on the following health consequences of cigarette smoking: age-related macular degeneration, cataracts, type 2 diabetes, peripheral vascular disease (amputation), bladder cancer, erectile dysfunction, head and neck cancer, heart disease and stroke, stunted fetal growth, and COPD. There were 2 revised warning statements that had statistically significant higher levels of *New information* but not *Self-reported learning*, both of which focused on pregnancy-related health consequences (premature birth; premature birth and low birth weight). An additional 2 revised warning statements had statistically significant

⁴ There was one exception: the statement focusing on lung disease in non-smokers was new information to 41.9% of participants.

higher levels of *Self-reported learning* but not *New information* (emphysema and chronic bronchitis; pneumonia). One revised warning statement did not have statistically significant higher levels of either of these two outcomes (mouth and throat cancer). Of the 5 revised warning statements that did not have statistically significant higher outcomes for both *New information* and *Self-reported learning*, 4 focused on a health topic for which there was another revised warning statement that had statistically significant higher levels of *New information and Self-reported learning* (e.g., premature birth vs. stunts fetal growth); only the revised warning statement on pneumonia did not.

For the other Phase 1 outcomes, both the TCA and revised warning statements made many participants think about the risks of smoking (50-70% of participants), but only 4 of the 15 revised statements were rated statistically significantly higher for *Thinking about the risks* when compared to a TCA warning statement, and 1 revised warning statement was rated statistically significantly lower than its comparator TCA warning statement. Similarly, health beliefs were overall high for both the TCA and revised warning statements, but only 4 of the 15 revised statements were rated statistically significantly higher for *Health beliefs* when compared to a TCA statement. However, when looking at the Phase 2 outcome results that compared sets of 9 revised warning statements to the 9 TCA warning statements, the revised warning statements demonstrated higher levels of *Health beliefs* overall compared to the TCA warning statements.

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Experimental Studies of Cigarette Warning Labels

Study 1 Methodology Report

Prepared for

David Portnoy & Shireen Ahmad

Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Prepared by

James Nonnemaker

Matthew Eggers

Jessica Pepper

Jesse Thompson

RTI International
3040 E. Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0212926.032
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2. Study Design

2.1 Experimental Design

Participants from 4 groups (adolescent smokers, adolescent nonsmokers susceptible to smoking, young adult smokers, and older adult smokers) were randomized to 1 of 16 experimental conditions or a control condition. Within each group, assignment to condition was conducted using a least-fill quota methodology whereby participants were iteratively assigned to the condition with the lowest current quota count, with quota thresholds set to achieve approximately the same number of participants per condition.

In Part 1 of Phase 1 of the study, participants in the control condition viewed all nine TCA text warning statements presented in a random order. Participants in each of the 16 experimental conditions viewed 8 of the TCA statements, plus 1 of the revised statements in a random order. The warning statements and study conditions are summarized in Tables 2-1 and 2-2. After viewing each statement, participants completed measures assessing new knowledge gained about a health effect, learning as a result of exposure to the warning statement, and the degree to which the statement makes them think about the health risks of smoking. The individual warning statement remained on the screen as they answered these questions, and the series of questions was repeated for each of nine warning statements in their assigned condition.

Table 2-1. Warning Statements

#	Statement
TCA	
S1	WARNING: Cigarettes are addictive.
S2	WARNING: Tobacco smoke can harm your children.
S3	WARNING: Cigarettes cause fatal lung disease.
S4	WARNING: Cigarettes cause cancer.
S5	WARNING: Cigarettes cause strokes and heart disease.
S6	WARNING: Smoking during pregnancy can harm your baby.
S7	WARNING: Smoking can kill you.
S8	WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
S9	WARNING: Quitting smoking now greatly reduces serious risks to your health.

(continued)

Table 2-1. Warning Statements (continued)

#	Statement
Revised	
R1A	WARNING: Smoking causes mouth and throat cancer.
R1B	WARNING: Smoking causes head and neck cancer.
R1C	WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
R2A	WARNING: Smoking during pregnancy causes premature birth.
R2B	WARNING: Smoking during pregnancy stunts fetal growth.
R2C	WARNING: Smoking during pregnancy causes premature birth and low birth weight.
R3A	WARNING: Secondhand smoke causes respiratory illnesses in children, like pneumonia.
R4A	WARNING: Smoking can cause heart disease and strokes by clogging arteries.
R5A	WARNING: Smoking causes COPD, a lung disease that can be fatal.
R5B	WARNING: Smoking causes serious lung diseases like emphysema and chronic bronchitis.
R6A	WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
R6B	WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
R7A	WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
R8A	WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
R8B	WARNING: Smoking causes cataracts, which can lead to blindness.

Note: In warning number, S = statutory and R = Revised.

Table 2-2. Study Conditions

Condition	Stimuli Slot (Randomize Order)								
	1	2	3	4	5	6	7	8	9
0 (CONTROL)	S1	S2	S3	S4	S5	S6	S7	S8	S9
1	S1	S2	S3	R1A	S5	S6	S7	S8	S9
2	S1	S2	S3	R1B	S5	S6	S7	S8	S9
3	S1	S2	S3	R1C	S5	S6	S7	S8	S9
4	S1	S2	S3	S4	S5	R2A	S7	S8	S9
5	S1	S2	S3	S4	S5	R2B	S7	S8	S9
6	S1	S2	S3	S4	S5	R2C	S7	S8	S9
7	S1	R3A	S3	S4	S5	S6	S7	S8	S9
8	S1	S2	S3	S4	R4A	S6	S7	S8	S9
9	S1	S2	S3	S4	S5	S6	S7	R5A	S9
10	S1	S2	R5A	S4	S5	S6	S7	S8	S9
11	S1	S2	R5B	S4	S5	S6	S7	S8	S9

(continued)

2-2

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Table 2-2. Study Conditions (continued)

Condition	Stimuli Slot (Randomize Order)								
	1	2	3	4	5	6	7	8	9
12	RANDOM SELECTION OF 8 OF 9 TCA ("S") STATEMENTS								R6A
13	RANDOM SELECTION OF 8 OF 9 TCA ("S") STATEMENTS								R6B
14	RANDOM SELECTION OF 8 OF 9 TCA ("S") STATEMENTS								R7A
15	RANDOM SELECTION OF 8 OF 9 TCA ("S") STATEMENTS								R8A
16	RANDOM SELECTION OF 8 OF 9 TCA ("S") STATEMENTS								R8B

In Part 2 of Phase 1, respondents were asked a series of questions assessing beliefs about the negative health consequences of smoking contained in the warning statements. This set of questions was asked once after viewing all nine of the statements in Part 1 of Phase 1, and the warning statements were not visible as the questions were presented.

In Phase 2, participants viewed a set of warning statements in a single exposure and then indicated their beliefs about the negative health consequences of smoking contained in the warning statements by selecting relevant health consequences from a list. In this phase, respondents were split into two groups: (1) a treatment group comprised of respondents in any of the experimental conditions from Phase 1; and (2) a control group comprised of respondents who were in the Phase 1 control group.

The Phase 2 treatment group respondents viewed a set of nine warnings comprised only of revised warning statements, with one randomly selected statement per topic area with the exception of statements focused on cancer (revised statements R1A, R1B, and R1C). Participants viewed two of the three randomly selected statements within that topic area. The eight topic areas, which are indicated in the statement number, were (1) cancer, (2) pregnancy, (3) secondhand smoke, (4) heart disease and stroke, (5) lung disease, (6) blood flow, (7) diabetes, and (8) vision-related.

Table 2-3 summarizes the procedure for selection of warning statements for the treatment group. Respondents in the control group viewed the same nine TCA warning statements they previously viewed, also presented as a set. After viewing their assigned set of statements, all respondents completed a final set of measures assessing beliefs about the health consequences of smoking contained in the warning statements.

3.3 Phase 1, Part 1 Results: Statement-Level Comparisons of Revised Statements to Corresponding or Randomized TCA Statements

3.3.1 Learning (Primary Outcome)

As shown in Table 3-4, participants' reports of learning new information were significantly higher for revised statements in 12 of 16 comparisons of revised to TCA statements. After controlling for age group, all of the following revised statements received higher ratings for learning than their control (TCA) statements: head and neck cancer (R1B), bladder cancer (R1C), stunt fetal growth (R2B), respiratory illness in children (R3A), clogged arteries (R4A), COPD (R5A; only when compared with fatal lung disease in smokers [S3]), emphysema and bronchitis (R5B), erectile dysfunction (R6A), amputation (R6B), diabetes (R7A), macular degeneration (R8A), and cataracts (R8B). All 12 statistically significant comparisons were significant both unadjusted and adjusted for multiple comparisons.

Table 3-4. Linear Regression of Learning (Primary Outcome) Comparing Revised Statements with Corresponding or Randomized TCA Statements

Comparison	Statements Being Compared	Learning: Mean (SD)	Regression Coefficient (95% CI)
1	Unspecified cancer (S4)	2.39 (2.08)	REF
	Mouth and throat cancer (R1A)	2.51 (2.09)	0.13 (−0.39 - 0.65)
2	Unspecified cancer (S4)	2.39 (2.08)	REF
	Head and neck cancer (R1B)	3.92 (1.77)	1.52 (1.05 - 1.99) ^{a,b}
3	Unspecified cancer (S4)	2.39 (2.08)	REF
	Bladder cancer (R1C)	4.19 (1.86)	1.81 (1.33 - 2.28) ^{a,b}
4	Harm your baby (S6)	2.43 (2.17)	REF
	Premature birth (R2A)	2.94 (2.24)	0.52 (−0.01 - 1.04)
5	Harm your baby (S6)	2.43 (2.17)	REF
	Stunt fetal growth (R2B)	3.17 (2.22)	0.75 (0.21 - 1.28) ^{a,b}
6	Harm your baby (S6)	2.43 (2.17)	REF
	Low birth weight (R2C)	2.93 (2.17)	0.52 (0 - 1.03)
7	Harm children (S2)	2.56 (2.15)	REF
	Respiratory illness in children (R3A)	3.30 (1.95)	0.73 (0.25 - 1.21) ^{a,b}
8	Strokes and heart disease (S5)	2.70 (1.96)	REF
	Clogged arteries (R4A)	3.36 (2.03)	0.66 (0.19 - 1.13) ^{a,b}
9	Fatal lung disease in nonsmokers (S8)	2.86 (1.99)	REF
	COPD (R5A)	3.26 (2.03)	0.41 (−0.07 - 0.88)

(continued)

Table 3-4. Linear Regression of Learning (Primary Outcome) Comparing Revised Statements with Corresponding or Randomized TCA Statements (continued)

Comparison	Statements Being Compared	Learning: Mean (SD)	Regression Coefficient (95% CI)
10	Fatal lung disease in smokers (S3)	2.33 (2.07)	REF
	COPD (R5A)	3.38 (2.00)	1.05 (0.56 - 1.53) ^{a,b}
11	Fatal lung disease in smokers (S3)	2.33 (2.07)	REF
	Emphysema and bronchitis (R5B)	3.19 (2.22)	0.86 (0.35 - 1.38) ^{a,b}
12	Random TCA statement (S6)	2.43 (2.17)	REF
	Erectile dysfunction (R6A)	3.85 (1.87)	1.42 (0.93 - 1.9) ^{a,b}
13	Random TCA statement (S5)	2.70 (1.96)	REF
	Amputation (R6B)	4.23 (1.78)	1.53 (1.09 - 1.97) ^{a,b}
14	Random TCA statement (S3)	2.33 (2.07)	REF
	Diabetes (R7A)	3.90 (1.92)	1.56 (1.09 - 2.03) ^{a,b}
15	Random TCA statement (S1)	2.25 (2.17)	REF
	Macular degeneration (R8A)	4.38 (1.72)	2.12 (1.64 - 2.6) ^{a,b}
16	Random TCA statement (S6)	2.43 (2.17)	REF
	Cataracts (R8B)	4.28 (1.81)	1.85 (1.38 - 2.33) ^{a,b}

^aSignificant at $p < .05$ in unadjusted analyses. ^bSignificant after adjustment for multiple comparisons.

Note: Regression controls for age group. CI = confidence interval. SD = standard deviation.

Out of 16 comparisons, the number of statistically significant comparisons showing greater learning for revised versus TCA statements was 13 for adolescents, 9 for young adults, and 7 for older adults. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-1 through B-3.

3.3.2 New Knowledge (Primary Outcome)

As shown in Table 3-5, participants were more likely to describe the smoking-related health conditions in the revised warnings as new knowledge in 12 of 16 comparisons of revised to TCA statements. Specifically, after controlling for age group, respondents were more likely to say that the health effect was new knowledge for each of the following revised statements relative to the TCA statements: head and neck cancer (R1B), bladder cancer (R1C), premature birth (R2A), stunt fetal growth (R2B), low birth weight (R2C), clogged arteries (R4A), COPD (R5A; only when compared with the control statement about fatal lung disease in smokers), erectile dysfunction (R6A), amputation (R6B), diabetes (R7A), macular degeneration (R8A), and cataracts (R8B). In all cases, comparisons were statistically significant even after controlling for multiple comparisons.

Table 3-5. Logistic Regressions of New Knowledge and Thinking about Risks (Primary Outcomes) Comparing Revised Statements with Corresponding or Randomized TCA Statements

Comparison	Statements Being Compared	New Knowledge		Thinking About Risks	
		Percent	OR (95% CI)	Percent	OR (95% CI)
1	Unspecified cancer (S4)	12.2	REF	68.9	REF
	Mouth and throat cancer (R1A)	12.9	1.07 (0.54 - 2.15)	68.0	0.96 (0.59 - 1.58)
2	Unspecified cancer (S4)	12.2	REF	68.9	REF
	Head and neck cancer (R1B)	64.2	13.26 (7.20 - 24.4) ^{a,b}	68.9	1.00 (0.61 - 1.64)
3	Unspecified cancer (S4)	12.2	REF	68.9	REF
	Bladder cancer (R1C)	78.9	28.15 (14.74 - 53.72) ^{a,b}	70.8	1.10 (0.66 - 1.81)
4	Harm your baby (S6)	8.8	REF	70.9	REF
	Premature birth (R2A)	17.6	2.28 (1.09 - 4.75) ^{a,b}	64.9	0.76 (0.46 - 1.24)
5	Harm your baby (S6)	8.8	REF	70.9	REF
	Stunt fetal growth (R2B)	19.0	2.49 (1.21 - 5.13) ^{a,b}	68.0	0.87 (0.53 - 1.44)
6	Harm your baby (S6)	8.8	REF	70.9	REF
	Low birth weight (R2C)	19.0	2.47 (1.21 - 5.03) ^{a,b}	68.0	0.87 (0.52 - 1.44)
7	Harm children (S2)	23.0	REF	68.9	REF
	Respiratory illness in children (R3A)	31.8	1.56 (0.93 - 2.63)	74.3	1.31 (0.79 - 2.17)
8	Strokes and heart disease (S5)	16.2	REF	66.9	REF
	Clogged arteries (R4A)	32.0	2.50 (1.41 - 4.43) ^{a,b}	64.6	0.90 (0.56 - 1.47)
9	Fatal lung disease in nonsmokers (S8)	41.9	REF	56.8	REF
	COPD (R5A)	36.7	0.80 (0.50 - 1.29)	71.4	1.94 (1.19 - 3.17) ^{a,b}
10	Fatal lung disease in smokers (S3)	16.2	REF	61.5	REF
	COPD (R5A)	29.3	2.14 (1.22 - 3.77) ^{a,b}	76.9	2.13 (1.27 - 3.56) ^{a,b}

(continued)

Table 3-5. Logistic Regressions of New Knowledge and Thinking about Risks (Primary Outcomes) Comparing Revised Statements with Corresponding or Randomized TCA Statements (continued)

Comparison	Statements Being Compared	New Knowledge		Thinking About Risks	
		Percent	OR (95% CI)	Percent	OR (95% CI)
11	Fatal lung disease in smokers (S3)	16.2	REF	61.5	REF
	Emphysema and bronchitis (R5B)	22.4	1.50 (0.83 - 2.72)	78.2	2.29 (1.36 - 3.84) ^{a,b}
12	Random TCA statement (S6)	8.8	REF	70.9	REF
	Erectile dysfunction (R6A)	69.4	24.43 (12.26 - 48.66) ^{a,b}	55.1	0.50 (0.30 - 0.81) ^{a,b}
13	Random TCA statement (S5)	16.2	REF	66.9	REF
	Amputation (R6B)	66.2	10.79 (6.10 - 19.08) ^{a,b}	77.7	1.75 (1.04 - 2.96) ^a
14	Random TCA statement (S3)	16.2	REF	61.5	REF
	Diabetes (R7A)	75.5	16.01 (8.97 - 28.57) ^{a,b}	56.5	0.81 (0.51 - 1.30)
15	Random TCA statement (S1)	8.8	REF	55.4	REF
	Macular degeneration (R8A)	75.5	36.90 (17.66 - 77.07) ^{a,b}	71.4	2.01 (1.24 - 3.26) ^{a,b}
16	Random TCA statement (S6)	8.8	REF	70.9	REF
	Cataracts (R8B)	79.7	42.61 (20.73 - 87.55) ^{a,b}	64.2	0.73 (0.45 - 1.20)

^aSignificant at $p < .05$ in unadjusted analyses. ^bSignificant after adjustment for multiple comparisons.

Note: Regressions control for age group. CI = confidence interval. OR = odds ratio.

Out of 16 comparisons, the number of statistically significant comparisons showing new knowledge for revised versus TCA statements was 14 for adolescents, 7 for young adults, and 8 for older adults. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-4 through B-6.

3.3.3 Thinking About Risks (Primary Outcome)

In 5 of the 16 comparisons also shown in Table 3-5, respondents were statistically significantly more likely to say that the revised warning statement made them think about the relevant health risk more than the TCA statement: COPD (R5A; when compared with both the statement about fatal lung disease in smokers and the statement about fatal lung

disease in nonsmokers), emphysema and bronchitis (R5B), amputation (R6B), and macular degeneration (R8B). Four of those five results were significant both unadjusted and adjusted for multiple comparisons; one (amputation (R6B)) was significant only unadjusted. For the warning statement related to erectile dysfunction (R6A), participants were significantly less likely to say that the statement made them think about the health condition than were participants who saw the randomly assigned TCA statement; this result was significant before and after adjustment for multiple comparisons.

Out of 16 comparisons, the number of statistically significant comparisons showing greater likelihood of thinking about health risks for revised versus TCA statements was 0 for adolescents, 2 for young adults, and 1 for older adults. Among adolescents, 1 comparison indicated lower likelihood of thinking about health risks for revised versus TCA statements. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-4 through B-6.

3.3.4 Believability (Secondary Outcome)

As shown in Table 3-6, respondents regarded **one revised statement (COPD [R5A]) as significantly more believable than its paired TCA statement (fatal lung disease in nonsmokers).** They perceived seven statements as less believable than their paired control statements: head and neck cancer (R1B), bladder cancer (R1C), erectile dysfunction (R6A), amputation (R6B), diabetes (R7A), macular degeneration (R8A), and cataracts (R8B). All significant associations maintained significance after adjusting for multiple comparisons.

Table 3-6. Linear Regressions of Believability and Informativeness (Secondary Outcomes) Comparing Revised Statements with Corresponding or Randomized TCA Statements

Comparison	Statements Being Compared	Believability		Informativeness	
		Mean (SD)	Regression Coefficient (95% CI)	Mean (SD)	Regression Coefficient (95% CI)
1	Unspecified cancer (S4)	4.80 (1.37)	REF	4.04 (1.81)	REF
	Mouth and throat cancer (R1A)	4.77 (1.33)	-0.03 (-0.33 - 0.28)	4.10 (1.69)	0.06 (-0.34 - 0.46)
2	Unspecified cancer (S4)	4.80 (1.37)	REF	4.04 (1.81)	REF
	Head and neck cancer (R1B)	3.72 (1.81)	-1.08 (-1.44 - -0.7) ^{a,b}	3.87 (1.73)	-0.17 (-0.57 - 0.23)
3	Unspecified cancer (S4)	4.80 (1.37)	REF	4.04 (1.81)	REF
	Bladder cancer (R1C)	3.69 (1.85)	-1.11 (-1.48 - -0.7) ^{a,b}	4.15 (1.80)	0.11 (-0.3 - 0.52)

(continued)

Table 3-6. Linear Regressions of Believability and Informativeness (Secondary Outcomes) Comparing Revised Statements with Corresponding or Randomized TCA Statements (continued)

Comparison	Statements Being Compared	Believability		Informativeness	
		Mean (SD)	Regression Coefficient (95% CI)	Mean (SD)	Regression Coefficient (95% CI)
4	Harm your baby (S6)	4.89 (1.30)	REF	4.14 (1.72)	REF
	Premature birth (R2A)	4.78 (1.37)	-0.10 (-0.4 - 0.2)	4.48 (1.54)	0.34 (-0.03 - 0.71)
5	Harm your baby (S6)	4.89 (1.30)	REF	4.14 (1.72)	REF
	Stunt fetal growth (R2B)	4.87 (1.39)	-0.01 (-0.31 - 0.29)	4.33 (1.72)	0.19 (-0.2 - 0.58)
6	Harm your baby (S6)	4.89 (1.30)	REF	4.14 (1.72)	REF
	Low birth weight (R2C)	4.77 (1.41)	-0.12 (-0.42 - 0.19)	4.43 (1.55)	0.29 (-0.08 - 0.66)
7	Harm children (S2)	4.49 (1.54)	REF	3.85 (1.75)	REF
	Respiratory illness in children (R3A)	4.59 (1.50)	0.11 (-0.23 - 0.45)	4.39 (1.50)	0.54 (0.17 - 0.91) ^{a,b}
8	Strokes and heart disease (S5)	4.51 (1.40)	REF	4.04 (1.70)	REF
	Clogged arteries (R4A)	4.55 (1.47)	0.04 (-0.28 - 0.37)	4.39 (1.52)	0.35 (-0.01 - 0.72)
9	Fatal lung disease in nonsmokers (S8)	3.74 (1.77)	REF	3.84 (1.82)	REF
	COPD (R5A)	4.69 (1.42)	0.95 (0.58 - 1.32) ^{a,b}	4.44 (1.55)	0.60 (0.21 - 0.99) ^{a,b}
10	Fatal lung disease in smokers (S3)	4.60 (1.48)	REF	3.93 (1.84)	REF
	COPD (R5A)	4.88 (1.20)	0.28 (-0.02 - 0.59)	4.72 (1.20)	0.79 (0.42 - 1.16) ^{a,b}
11	Fatal lung disease in smokers (S3)	4.60 (1.48)	REF	3.93 (1.84)	REF
	Emphysema and bronchitis (R5B)	4.85 (1.41)	0.26 (-0.07 - 0.58)	4.37 (1.63)	0.44 (0.05 - 0.84) ^a
12	Random TCA statement (S6)	4.89 (1.30)	REF	4.14 (1.72)	REF
	Erectile dysfunction (R6A)	3.93 (1.65)	-0.95 (-1.28 - -0.6) ^{a,b}	4.00 (1.74)	-0.14 (-0.53 - 0.25)

(continued)

Table 3-6. Linear Regressions of Believability and Informativeness (Secondary Outcomes) Comparing Revised Statements with Corresponding or Randomized TCA Statements (continued)

Comparison	Statements Being Compared	Believability		Informativeness	
		Mean (SD)	Regression Coefficient (95% CI)	Mean (SD)	Regression Coefficient (95% CI)
13	Random TCA statement (S5)	4.51 (1.40)	REF	4.04 (1.70)	REF
	Amputation (R6B)	3.96 (1.68)	-0.55 (-0.9 - -0.1) ^{a,b}	4.37 (1.54)	0.33 (-0.03 - 0.7)
14	Random TCA statement (S3)	4.60 (1.48)	REF	3.93 (1.84)	REF
	Diabetes (R7A)	3.72 (1.93)	-0.87 (-1.26 - -0.4) ^{a,b}	4.01 (1.92)	0.08 (-0.35 - 0.5)
15	Random TCA statement (S1)	4.74 (1.64)	REF	3.57 (1.98)	REF
	Macular degeneration (R8A)	3.93 (1.69)	-0.82 (-1.19 - -0.4) ^{a,b}	4.21 (1.68)	0.63 (0.21 - 1.05) ^{a,b}
16	Random TCA statement (S6)	4.89 (1.30)	REF	4.14 (1.72)	REF
	Cataracts (R8B)	3.76 (1.79)	-1.13 (-1.48 - -0.7) ^{a,b}	4.17 (1.76)	0.03 (-0.37 - 0.42)

^aSignificant at $p < .05$ in unadjusted analyses. ^bSignificant after adjustments for multiple comparisons.

Note: Regressions control for age group. CI = confidence interval. SD = standard deviation.

Out of 16 comparisons, the number of statistically significant comparisons showing lower believability for revised versus TCA statements was 7 for adolescents, 5 for young adults, and 5 for older adults. In 1 comparison for adolescents, 1 comparison for young adults, and 1 comparison for older adults, revised statements were rated as more believable than TCA statements. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-7 through B-9.

3.3.5 Informativeness (Secondary Outcome)

Also shown in Table 3-6, respondents considered the revised statement to be more informative in 5 of the 16 comparisons of revised to TCA statements: respiratory illness in children (R3A), COPD (R5A; compared with both of its control statements), emphysema and bronchitis (R5B), and macular degeneration (R8A). Aside from the revised statement on emphysema and bronchitis, all of these results were still significant after adjustment for multiple comparisons.

Out of 16 comparisons, the number of statistically significant comparisons showing that revised versus TCA statement was more informative was 1 for adolescents, 2 for young

adults, and 0 for older adults. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-7 through B-9.

3.3.6 Factuality (Secondary Outcome)

Also shown in Table 3-7, within each experimental condition, most respondents reported that the statements were factual, ranging from a low of 56.1% thinking that the statement on head and neck cancer was factual to a high of 92.5% for COPD. Respondents were less likely to consider the following revised statements to be factual, compared with the TCA statements: head and neck cancer (R1B), bladder cancer (R1C), erectile dysfunction (R6A), amputation (R6B), diabetes (R7A), macular degeneration (R8A), and cataracts (R8B). Respondents were more likely to consider the revised statement about COPD (R5A) factual than the statement about fatal lung disease in nonsmokers. All findings were significant before and after adjustment for multiple comparisons.

Table 3-7. Logistic Regression of Factuality (Secondary Outcome) Comparing Revised Statements with Corresponding or Randomized TCA Statements

Comparison	Statements Being Compared	Factuality	
		Percent	OR (95% CI)
1	Unspecified cancer (S4)	87.2	REF
	Mouth and throat cancer (R1A)	88.4	1.13 (0.56 - 2.3)
2	Unspecified cancer (S4)	87.2	REF
	Head and neck cancer (R1B)	56.1	0.18 (0.1 - 0.33) ^{a,b}
3	Unspecified cancer (S4)	87.2	REF
	Bladder cancer (R1C)	69.4	0.32 (0.17 - 0.59) ^{a,b}
4	Harm your baby (S6)	87.8	REF
	Premature birth (R2A)	83.1	0.68 (0.35 - 1.31)
5	Harm your baby (S6)	87.8	REF
	Stunt fetal growth (R2B)	79.6	0.54 (0.28 - 1.01)
6	Harm your baby (S6)	87.8	REF
	Low birth weight (R2C)	87.8	1.00 (0.49 - 2.02)
7	Harm children (S2)	75.7	REF
	Respiratory illness in children (R3A)	82.4	1.52 (0.86 - 2.7)
8	Strokes and heart disease (S5)	83.8	REF
	Clogged arteries (R4A)	81.0	0.82 (0.44 - 1.51)
9	Fatal lung disease in nonsmokers (S8)	61.5	REF
	COPD (R5A)	83.0	3.20 (1.82 - 5.61) ^{a,b}

(continued)

Table 3-7. Logistic Regression of Factuality (Secondary Outcome) Comparing Revised Statements with Corresponding or Randomized TCA Statements (continued)

Comparison	Statements Being Compared	Factuality	
		Percent	OR (95% CI)
10	Fatal lung disease in smokers (S3)	85.8	REF
	COPD (R5A)	92.5	2.06 (0.95 - 4.5)
11	Fatal lung disease in smokers (S3)	85.8	REF
	Emphysema and bronchitis (R5B)	91.8	1.90 (0.89 - 4.06)
12	Random TCA statement (S6)	87.8	REF
	Erectile dysfunction (R6A)	65.3	0.24 (0.13 - 0.44) ^{a,b}
13	Random TCA statement (S5)	83.8	REF
	Amputation (R6B)	68.9	0.42 (0.24 - 0.74) ^{a,b}
14	Random TCA statement (S3)	85.8	REF
	Diabetes (R7A)	61.2	0.25 (0.14 - 0.45) ^{a,b}
15	Random TCA statement (S1)	79.7	REF
	Macular degeneration (R8A)	65.8	0.49 (0.29 - 0.83) ^{a,b}
16	Random TCA statement (S6)	87.8	REF
	Cataracts (R8B)	61.5	0.20 (0.11 - 0.37) ^{a,b}

^aSignificant at $p < .05$ in unadjusted analyses. ^bSignificant after adjustment for multiple comparisons.

Note: Regression controls for age group. CI = confidence interval. OR = odds ratio.

Out of 16 comparisons, the number of statistically significant comparisons in which participants rated the revised statement as less factual than the TCA statements was 6 for adolescents, 5 for young adults, and 6 for older adults. In 1 comparison for young adults and 1 comparison for older adults, participants rated the revised statements as more factual than the TCA statements. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-10 through B-12.

3.4 Phase 1, Part 1 Results: Statement-Level Comparisons of Revised Statements to No Statements

We conducted additional analyses for the five revised statements without matching control statements (erectile dysfunction, amputation, diabetes, macular degeneration, and cataracts). Based on results from linear regression models, the mean ratings for all five statements were significantly higher than zero (i.e., “not at all”) for learning, believability, and informativeness. Based on results from logistic regression models, the proportion of respondents indicating that the statement was new knowledge, thought about the health risks of smoking, and believed the statement to be factual was also significantly greater than zero for all five of the revised statements. In all cases, the results were still statistically

significant after controlling for multiple comparisons. The same pattern occurred within each of the groups (adolescent, young adult, and older adult): all comparisons between revised statements and zero (i.e., no statement) were significantly different in the expected direction both before and after controlling for multiple comparisons.

3.5 Phase 1, Part 2 Results: Condition-Level Comparisons of Health Beliefs

For the Phase 1, Part 2 analysis, we conducted condition-level comparisons for key measures assessing beliefs about the negative health consequences of smoking contained in the warning statements. For each experimental condition, the survey includes an item or series of items in which respondents are asked to rate their level of agreement with a statement about a negative health consequence corresponding to the warning statement for that condition. The number of items associated with a particular warning statement ranges from 1 to 4, and the items were asked once following viewing of warning statements for all respondents.

The health belief items in Phase 1 have Likert response scales. Conceptually, the response categories for a Likert response scale represent an underlying belief continuum. For warning statements with multiple corresponding items, we assessed whether the items could be appropriately scaled for use in linear regressions.

As part of our assessment on items' scalability, we ran a test of internal consistency reliability using Cronbach's alpha for all of the warning statements with multiple corresponding items (Cronbach, 1951). If this test indicated modest reliability (alpha greater than or equal to 0.70), we scaled the items (Nunnally & Bernstein, 1994). Furthermore, if the alpha was less than 0.70, but all item-total correlations are greater than or equal to 0.40, we also scaled the items. This decision was based on evidence in the literature that item-correlations between 0.30 and 0.40 have been suggested as sufficiently discriminating (Nunnally & Bernstein, 1994; Traub, 1994; Leong & Austin, 2006).

There were 12 warning statements that were potentially scalable (i.e., had multiple items). Of these 12 warning statements with multiple items, 11 had an alpha of greater than 0.70 and were thus scaled (Appendix Table B-13). The revised warning statement related to smoking and development of emphysema and bronchitis had an alpha of 0.69 but had item-total correlations of greater than 0.40. Therefore, the items corresponding to the revised emphysema and bronchitis statement were also scaled.

Three warning statements (premature birth [R2A], stunt fetal growth [R2B], and low birth weight [R2C]) could not be scaled because there was only one associated health belief per statement. We used the Brant test (Brant, 1990; Williams, 2005) to confirm that the proportional odds assumption (i.e., the explanatory variable has the same effect across all the ordinal categories of the dependent variable) was not violated (all chi-square statistics

non-significant at $p > .05$). Because the assumption was not violated, we analyzed these items using ordinal logistic regression.

3.5.1 Results of Linear Regressions for Scaled Outcomes

Of our 13 linear regression models, 8 produced significant results indicating that the revised warning statement was associated with higher health belief scores than the control (Table 3-8). The following eight revised statements all had higher mean health belief scores than their control statements: mouth and throat cancer (R1A), COPD (R5A; only when compared with fatal lung disease in smokers), emphysema (R5B), erectile dysfunction (R6A), amputation (R6B), diabetes (R7A), macular degeneration (R8A), and cataracts (R8B). Four comparisons were significant both before after adjusting for multiple comparisons and four comparisons were only significant before adjustment.

Out of 13 comparisons, the number of statistically significant comparisons showing higher health belief scores for revised versus TCA statements was 1 for adolescents, 5 for young adults, and 1 for older adults. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-14 through B-16.

3.5.2 Results of Ordinal Logistic Regressions for Non-Scaled Outcomes

Table 3-9 shows the results of the ordinal regressions for the revised statements (i.e., premature birth [R2A], stunted fetal growth [R2B], and low birth weight [R2C]) that only involved one health belief. For all three, there were no significant differences between the revised and control statements in the proportion of respondents endorsing each response category.

Out of 3 comparisons, there was 1 comparison for young adults and 1 comparison for older adults in which respondents endorsed higher levels of agreement with the health belief for revised compared to TCA statements. There were no statistically significant differences for comparisons among adolescent respondents. Complete results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-17 through B-19.

Table 3-8. Linear Regressions for Condition-Level Comparisons of Health Beliefs in Phase 1

Comparison	Statements Being Compared	Mean (SD) Health Belief Score		Regression Coefficients (95% CI)
		Treatment ^c	Control ^c	
1	Mouth and throat cancer (R1A) vs. Unspecified cancer (S4)	4.27 (0.74)	3.98 (0.93)	0.29 (0.1 - 0.48) ^{a,b}
2	Head and neck cancer (R1B) vs. Unspecified cancer (S4)	3.43 (1.00)	3.33 (1.05)	0.10 (-0.14 - 0.33)
3	Bladder cancer (R1C) vs. Unspecified cancer (S4)	3.41 (1.01)	3.26 (0.97)	0.15 (-0.07 - 0.38)
7	Respiratory illness in children (R3A) vs. Harm children (S2)	3.98 (0.87)	3.82 (0.90)	0.17 (-0.03 - 0.37)
8	Clogged arteries (R4A) vs. Strokes and heart disease (S5)	4.00 (0.88)	3.89 (0.83)	0.12 (-0.08 - 0.32)
9	COPD (R5A) vs. fatal lung disease in nonsmokers (S8)	4.32 (0.64)	4.18 (0.80)	0.14 (-0.03 - 0.3)
10	COPD (R5A) vs. fatal lung disease in smokers (S3)	4.38 (0.71)	4.18 (0.80)	0.19 (0.02 - 0.37) ^a
11	Emphysema and bronchitis (R5B) vs. fatal lung disease in smokers (S3)	4.25 (0.60)	4.06 (0.78)	0.19 (0.03 - 0.35) ^a
12	Erectile dysfunction (R6A) vs. random TCA statement (S6)	3.74 (0.91)	3.52 (0.81)	0.22 (0.02 - 0.42) ^a
13	Amputation (R6B) vs. random TCA statement (S5)	3.75 (0.84)	3.48 (0.93)	0.27 (0.07 - 0.47) ^{a,b}
14	Diabetes (R7A) vs. random TCA statement (S3)	3.48 (0.98)	3.10 (1.01)	0.38 (0.15 - 0.61) ^{a,b}
15	Macular degeneration (R8A) vs. random TCA statement (S1)	3.57 (0.95)	3.21 (0.93)	0.35 (0.14 - 0.57) ^{a,b}
16	Cataracts (R8B) vs. random TCA statement (S6)	3.37 (1.10)	3.13 (1.02)	0.24 (0.00 - 0.48) ^a

^aSignificant at $p < .05$ in unadjusted analyses. ^bSignificant after adjustments for multiple comparisons. ^cSpecific health belief items vary by condition: see Appendix A with study instrument for specific items.

Note: CI = confidence interval. SD = standard deviation.

Table 3-9. Ordinal Regressions for Condition-Level Comparisons of Health Beliefs in Phase 1

Comparison	Comparison and Level of Endorsement for Health Belief	Proportion Endorsing Each Response Level, %		OR (95% CI)
		Treatment ^a	Control ^a	
4	Premature birth (R2A) vs. Harm your baby (S6)			0.94 (0.62 - 1.45)
	1 "Strongly disagree" (Ref)	4.0	2.0	—
	2 "Disagree"	2.0	5.4	—
	3 "Neither agree nor disagree"	17.6	17.6	—
	4 "Agree"	38.5	33.1	—
	5 "Strongly agree"	37.2	41.2	—
5	Stunt fetal growth (R2B) vs. Harm your baby (S6)			1.46 (0.95 - 2.25)
	1 "Strongly disagree" (Ref)	2.7	2.7	—
	2 "Disagree"	2.7	6.1	—
	3 "Neither agree nor disagree"	8.9	16.2	—
	4 "Agree"	40.8	35.8	—
	5 "Strongly agree"	42.9	37.8	—
6	Low birth weight (R2C) vs. Harm your baby (S6)			1.48 (0.96 - 2.27)
	1 "Strongly disagree" (Ref)	1.4	2.7	—
	2 "Disagree"	4.1	5.4	—
	3 "Neither agree nor disagree"	17.0	15.5	—
	4 "Agree"	29.9	39.9	—
	5 "Strongly agree"	47.6	34.5	—

Note: CI = confidence interval. OR = odds ratio.

statements were significantly higher than 0 (i.e., “not at all”) for learning, believability, and informativeness. The proportion of respondents indicating that the information was new knowledge, made them think about the health risks of smoking, and was factual was also significantly greater than zero for all five of the revised statements without corresponding health conditions in the TCA warnings.

Finally, the Phase 2 results, comparing health beliefs for the set of revised statements to the set of TCA statements, suggests that the revised statements led to improved understanding of the health effects of smoking and secondhand smoke.

Summaries of the results for the adolescent, young adult, and older adult groups appear in Appendix Tables B-23 through B-25.

4.2 Limitations

Some limitations of this study are common to many online studies. For example, the stimuli being tested (in this case, warning statements) were not displayed in a naturalistic fashion but rather on a computer screen. A single session of exposure to stimuli may not be enough to generate change in knowledge or beliefs. Further, conclusions from this study can only be drawn about the stimuli presented, not about warnings in general.

There are also additional, study-specific limitations. Although the universe of respondents included four groups (adolescents susceptible to smoking, adolescent current smokers, young adult current smokers, and older adult current smokers), we did not have power to look for within-group differences. A deviation from protocol in how respondents were allocated to condition (described in more detail in the Methodology Report) resulted in fewer people in the control condition than originally planned, although it did not compromise randomization. Because of the error, there was less power to detect differences and results are conservative.

In addition, the survey used a **convenience sample** rather than a probability sample, and the results are not nationally representative. Generating a representative sample of the size necessary for this study would have been cost prohibitive. Despite the attempt to match the study’s sample and the respondent universe in four demographic characteristics, matching was used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics. Despite best efforts to have the study population reflect the demographic makeup of the larger population, the nature of convenience samples still limits the generalizability of the results from this study. These limitations in generalizability do not affect the internal validity of the study.